05-09-03

AF/#/GP1615

CASE 4-21233/A/PCT

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV268930305US	May 8, 2003
Express Mail Label Number	Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
BURKHARD SCHLÜTERMANN
APPLICATION NO: 09/367,361
FILED: AUGUST 11, 1999
FOR: OXACARBAZEPINE FILM-COATED TABLETS

Art Unit: 1615
Examiner: JAMES M. SPEAR

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Enclosed herewith are three copies of the Appeal Brief in the above-identified application.

☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of $320 for payment of the appeal fee. An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis.

☐ Enclosed is a Petition for Extension of Time.

Respectfully submitted,

John Thallemer

John D. Thallemer
Attorney for Applicant
Reg. No. 34,940

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
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Date: May 8, 2003

#18 4C

CASE 4-21233A 5/20/03

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Assistant Commissioner for Patents
Washington, D.C. 20231

APPEALLANT'S BRIEF UNDER 37 C.F.R. §1.192

Sir:

This brief is in furtherance of the Notice of Appeal filed in the above-identified application on May 5, 2003. This brief is transmitted in triplicate.

(1) REAL PARTY IN INTEREST

The real party in interest in the above-identified Appeal is Novartis AG, a company organized under the laws of the Swiss Confederation, of 4002 Basel Switzerland.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(3) STATUS OF CLAIMS

The claims on appeal are claims 16-20, all of the pending claims in the application.

(4) STATUS OF AMENDMENTS

A "Response to Final Rejection" was considered by the Examiner. No amendment to the claims or specification has been made after final rejection.

(5) SUMMARY OF THE INVENTION

The invention relates to a film-coated tablet having a tablet core and a single hydrophilic permeable coating. The tablet core contains oxacarbazepine and excipients. The oxacarbazepine has a median particle size of approximately 2 µm to 12 µm, and a maximum residue on a 40 µm sieve of less than or equal to 5%.

(6) ISSUES ON APPEAL

Whether claims 16-20 are unpatentable under 35 U.S.C. §103 over Bourquin, U.S. Patent No. 5,472,714.

(7) GROUPING OF CLAIMS

The claims stand or fall together.

(8) ARGUMENTS

Claims 16-20 are patentable over Bourquin.

Initially it is noted that "oxcarbazepine" and "oxacarbazepine" are equivalents according to The Merck Index, thirteenth edition.

Bourquin describes double-layered oxcarbazepine tablets. Bourquin states in column 1, lines 3-4, that the "invention relates to double-layered tablets for the therapeutic drug oxcarbazepine". Bourquin found that tablets containing oxcarbazepine have a storage problem in that during storage at room temperature, an inhomogeneous, faintly orange discoloration of the original white tablet is observed, and that the unwanted discoloration is caused by the formation of an oxidation product of oxcarbazepine, as stated by Bourquin in column 1, lines 15-21.

Bourquin further determined that the addition of a pigment, iron(II) oxide (FeO), during compression of the tablets provides a homogeneous yellowish-orange discoloration of the tablets. However, Bourquin noted in column 1, lines 35-45, that the use of greater than 5 mg of iron daily is prohibited by the Food and Drug Administration due to the physiological action of iron.

To overcome the discoloration problem and provide color stable tablets while maintaining a maximum daily ingestion of iron of 5 mg, Bourquin teaches tablets which have a tablet core containing oxcarbazepine; a hydrophilic, permeable inner layer containing white pigments; and a hydrophilic, permeable outer layer containing white pigments and iron(II) oxide. The tablet cores

are coated with the inner layer, followed by coating with the outer layer, as stated in column 4, lines 53-61. Such tablets according to Bourquin, "retain their homogenous yellowish colouration for a very long time", as stated in column 1, lines 65-66,.

In contrast to the teachings of Bourquin, Appellant achieves color and storage stability in oxacarbazepine tablets using only a single coating on the tablet core, as stated in Appellant's application, as originally filed, on page 2, lines 16-20. Appellant unexpectedly determined that color stability is achieved using only a single coating provided that the oxacarbazepine has a fine particle size and a narrow particle size distribution. Appellant defines particle size and particle size distribution for oxacarbazepine in the application on page 6, lines 9-13, as a median particle size of approximately 2 µm to 12 µm, and a maximum residue on a 40 µm sieve of less than or equal to 5%.

The only mention Bourquin makes of particle size is in Example 1 where Bourquin prepares oxacarbazepine tablets by compacting a mixture of oxacarbazepine and excipients to 2-6 mm coarse granules. It is noted, however, that excipients are included with the oxacarbazapine in the tablet core.

(9) CONCLUSION

In summary, the selection of oxacarbazepine having a median particle size of approximately 2 µm to 12 µm, and a maximum residue on a 40 µm sieve of less than or equal to 5% in order to make a tablet having color and storage stability is simply not taught or suggested by Bourquin. In addition, a single hydrophilic permeable coating is not taught or suggested by Bourquin. In fact, Bourquin clearly teaches away from using a single hydrophilic permeable coating. Thus, 35 U.S.C. §103 compels a conclusion of non-obviousness.

Appellants respectfully request that the rejection under 35 U.S.C. §103 by the Examiner be reversed and the pending claims 16-20 be passed to allowance.

Respectfully submitted,

John Thallemer

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Encl.: Appendix of Claims on Appeal
Date: May 8, 2003

(10) APPENDIX - THE CLAIMS ON APPEAL

16. A film-coated tablet comprising:
a) a tablet core comprising a therapeutically effective dose of oxacarbazepine and excipients that are suitable for the production of granules, wherein said oxacarbazepine has a median particle size of approximately 2 µm to 12 µm, and a maximum residue on a 40 µm sieve of less than or equal to 5%; and
b) a single hydrophilic permeable coating.

17. The tablet according to Claim 16 wherein the oxacarbazepine has a median particle size of approximately 4 µm to 10 µm.

18. The tablet according to Claim 17 wherein the oxacarbazepine has a median particle size of approximately 6 µm to 8 µm.

19. The tablet according to Claim 16 wherein the oxacarbazepine has a maximum residue on a 40 µm sieve of less than or equal to 2%.

20. The tablet according to Claim 16 wherein the hydrophilic permeable coating comprises white pigments and iron oxide pigments.